

REMARKS

Claims 1 to 13 and 17 to 24 are in the application. Claims 14 to 16 are cancelled. Claim 24 has been added. Claims 1, 2, 3, 6, 7, 13 and 17 to 21 have been amended. Support for the amendments to the claims lie in the working examples or in the specification on page 3, lines 1 to 25; page 3, lines 6 to 11, and lines 16 to 21; and page 6, lines 5 to 21. No new matter is believed added.

The Examiner has requested that Applicants "amend the first line of the specification to reiterate the claim to priority to PCT/EP99/06423." The present application is the national stage entry under §371 from PCT/EP99/06423, and which claims priority to GB 9819530.8. There is no claim to a US priority application under 35 USC §120 which is the basis for amendment to the specification. The correct method for a claim to priority under 35 USC §119 is by declaration which has properly been filed.

A supplemental Information Disclosure Statement and PTOL 1449 with references will be forwarded under separate cover.

Rejection under 35 USC §112

Claims 1, 4 to 14, 17 and 18 are rejected under 35 USC 112, 1st paragraph as being nonenabling for "viscosity modulating polymers" (VMP). Applicants respectfully traverse this rejection.

The Examiner comments that the specification is enabled for lowering tooth erosion potential using "complex" polysaccharides, but not "viscosity modulating polymers" (VMP) generally. The specification clearly teaches that VMP's includes complex polysaccharides, thickening agents, and stabilizers, and provides a listing of suitable agents thereof. Polyvinylpyrrolidinone (PVP) is also included as a VMP (page 3, lines 1 to 7). Applicants are not required to provide actual examples of every aspect of the invention. Thickening agents are a well recognized group of excipients in this art. The ordinary person would therefore not have difficulty understanding what is encompassed by this term. The specification provides adequate exemplification of the use of VMP's in the instant invention, see Example 4 which demonstrates 14 different thickening agents, Example 5 an additional 3, and Example 11 demonstrates use of PVP. Consequently, the specification is believed to meet the enablement requirement for use of viscosity modulating polymers.

Claims 2 and 20 are rejected under 35 USC 112, 2nd paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection.

The Examiner states that the term “complex” in claims 2 and 20 is a relative term which renders the claim indefinite”. The Examiner further states that the term “complex” is not defined by the claims and the specification does not provide a standard, and further that no “guidance is provided as to how “simple” a given polysaccharide must be to be outside the scope of the instant invention” (page 5, ¶ 1 Office Action).

Use of the term “complex polysaccharide” by Applicant is also not believed to be unusual. It is again, an art recognized term, as is the term “viscosity modulating polymer”. Applicants can act as their own lexicographer, and as such have defined the term “viscosity modulating polymer” in the specification, page 3, lines 1 to 7 to include food grade complex polysaccharides, stabilizers and thickening agents such as alginates, locust bean gum, gellan gum, guar gum, gum Arabic, tragacanth, carragenen, acacia gum, xanthan gum, pectin, cellulose derivatives, or a combination or mixture thereof.”. The specification further defines the preferred complex polysaccharide materials on page 5, lines 9 to 25. Therefore it is not seen how this is indefinite. However, Applicants have amended Claims 1, 2 and 20 (and others) to remove the term “complex” in order to further prosecution on the merits. Applicants retain their right to file divisional or continuation applications on deleted or cancelled subject matter.

In view of these Remarks and amendments, reconsideration and withdrawal of the rejection to the claims under 35 USC §112 is respectfully requested.

Rejection under 35 USC §102(b)

Claims 1 to 14 and 16 to 23 are rejected under 35 USC §102(b) as being anticipated by Montezinos (US 5,792,502 (hereinafter ‘502)). Applicants respectfully traverse this rejection.

The ‘502 patent relates to beverages with stable emulsions and/or cloud emulsions. There is no teaching in US ‘502 of reduction of tooth erosion caused by acidic solutions, nor is there a teaching of reduction of tooth erosion potential of an acidic beverage. The Examiner comments that the preamble is not limiting on the claim. While this is not legally a correct statement by the Examiner, Applicants have amended the claim to more particularly point out and distinctly claim the invention.

The ‘502 patent also does not teach the addition of calcium to the beverages. The Examiner comments that “any addition of calcium, no matter how minor, would be sufficient to anticipate claims 6, 7, 16 and 19”. Claim 1 has been amended to add the subject matter of Claim 6 wherein calcium is added to the composition, and its addition is

calculated on a molar basis relative to the molarity of the acidulant present in the composition. It is not the absolute concentration in the formulation that is important. It is the mole ratio of calcium to acid which is important, and as such that the molecular weights of the actual acids present in the compositions must be known in order to calculate this ratio.

The '502 patent does not teach addition of a molar ratio of calcium to acid. The '502 patent does not teach use of a VMP + a calcium compound to reduce the tooth erosion potential of an acidic composition. Therefore, Claims 1, 6, and 7 are not anticipated by this reference. Claim 16 has been cancelled, and Claim 19 has been amended to recite PVP as the viscosity modulating polymer. PVP is not disclosed in the '502 patent. Therefore it is believed that all of the claims in the instant application are not anticipated by the '502 patent.

Claims 13 to 23 are rejected under 35 USC §102(b) as being anticipated by Heckert (US 4,722,847 (hereinafter '847)). Applicants respectfully traverse this rejection.

The '847 relates to compositions specifically supplemented with significant levels of solubilized calcium and a process for making them. The disclosure, and use of the compositions of Heckert do not relate to reduction of tooth erosion by its administration. Heckert does not teach a process of reducing tooth erosion caused by acidic beverages, nor does it teach the reduction of the tooth erosion potential of acidic beverages. It does not teach how to achieve such compositions which could be used for this method.

More specifically, the '847 does not teach addition of viscosity modulating polymers, and control of the calcium to acid mole ratio for reduction of tooth erosion.

The '847 patent does not teach control of the pH of the resulting composition. The Examiner has misunderstood what is meant by the term 'if necessary or desired'. The term "if necessary or desired" means that the pH of the composition may be adjusted, either to bring the pH into the defined range (necessary) or to alter the pH within the defined range (desired) such that the pH is less than or equal to 4.5. This is not believed to recite an optional possibility, the pH need to be at 4.5 or below.

Therefore it is believed that all of the claims in the instant application are not anticipated by the '502 patent.

In view of these Remarks and Amendments, reconsideration and withdrawal of the rejection to the claims under 35 USC §102(b) is respectfully requested.

Rejection under 35 USC §103

Claims 1 to 14, and 16 to 23 are rejected under 35 USC §103(a) as being unpatentable over WO 97/30601 in view of Heckert (US 4,722,847).

Claims 1 to 14 and 16 to 23 are rejected under 35 USC §103(a) as being unpatentable over Parker (US 6,719,963) in view of Heckert (US 4,722,847).

Claims 1 to 14 and 16 to 23 are rejected under 35 USC §103(a) as being unpatentable over Parker (US 6,319,490) in view of Heckert (US 4,722,847). Applicants respectfully traverse these rejections.

WO 97/30601 is the publication of PCT application EP97/00646. US 6,319,490 is the §371 national stage entry of this PCT application, and US 6,719,963 is a divisional application from the '490 patent. Consequently, as the specifications of the 3 reference are the same the rejections will all be discussed together.

The Examiner states that the primary reference, Parker et al., discloses tooth erosion inhibiting oral compositions for use in beverages. The primary references differing from the instant claims "insofar as it is silent regarding inclusion of a "viscosity modulating" polymer. The Examiner is basically arguing that it would be obvious to add VMP's to the compositions as described in Parker et al. reference to prevent "the crystallisation of calcium added thereto, as taught by the secondary references".

The Parker et al. references relate to compositions and the use of calcium and acid in a specified ratio (0.3 to 0.75) with a pH in the range 3.5 to 4.5. There is no teaching, nor suggestion in the Parker et al. references why a person skilled in the art would look at them and think that there is a problem with stabilization of the calcium. The amount of calcium utilised therein does not have a problem with solubility, and stability – see '963, Column 2, lines 26 – 53. Consequently, the Examiner's statement is unfounded. The argument is lacking in that there would be a motivation to add a thickening agent to stabilize a composition which is not known to need it. This is a mere hindsight rejection on the Examiner's part.

The Heckert '847 patent does not teach nor suggest that the compositions disclosed therein have any positive use against tooth erosion caused by acidic beverages. In general, the calcium to acid molar ratios of the Examples in US '847 are from 0.77 to 1.72.

The present invention which is directed to the use of VMP's has been found to reduce tooth erosion potential of acidic compositions. It is certainly contemplated that one could build upon the knowledge disclosed by the Parker et al. patents. In

fact, the specification clearly discloses such on page 2, lines 21 to 25; and page 6, lines 33 and page 6, lines 1 to 29.

The specification has a number of working examples which teach use of a VMP (without addition of a calcium compound) for reduction of tooth erosion. The Examiner's attention is directed to pages 8, lines 14 to end through page 14, line 17. The addition of calcium to a VMP formulation is disclosed in Example 7, page 14, lines 19 to end, and on page 15, lines 1 to 4.

The Parker et al. patents do not teach nor suggest inclusion of a VMP to assist in reduction of the tooth erosion potential of an acidic composition. This failure is not achieved by reliance on the secondary reference of Heckert et al., '847. There is no need, nor any teaching to suggest that inhibition of the crystallization of added calcium is a problem. Therefore, the artisan would not look to the Heckert et al. patent for a solution to a problem which did not exist.

In view of these Remarks, reconsideration and withdrawal of the rejection to the claims under 35 USC §103 is respectfully requested.

Obvious Double Patenting Rejection

Claims 1 to 14, and 16 to 23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 20 of US Patent 6,719,963 in view of Heckert et al., US 4,722,847.

Claims 1 to 14, and 16 to 23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 20 of US Patent 6,719,490 in view of Heckert et al., US 4,722,847.

Claims 1 to 14, and 16 to 23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 20 of USN 10/733,992 in view of Heckert et al., US 4,722,847.

USSN 10/733,992 has now granted as US Patent 6,908,909.

As discussed above under the 35 USC §103 rejection, the Parker et al. set of patents and publications does not disclose a method of reducing tooth erosion by adding to an acidic composition a viscosity modulating polymer. While the claims herein have been amended to include addition of a calcium compound, there is no teaching or suggestion in the Parker et al. patent to direct the ordinary person in the art to include a viscosity modifying polymer to reduce tooth erosion of the acidic composition. This failure is not achieved by reliance on the secondary reference of Heckert et al., '847. There is no need, nor any teaching to suggest that inhibition of the crystallization of added calcium is a

problem. Therefore, the artisan would not look to the Heckert et al. patent for a solution to a problem which did not exist.

In view of these Remarks, it is believed that the claims of the Parker et al. patents do differ significantly from the claims herein and that terminal disclaimers over the claims of the three US patents is unwarranted at this time.

Reconsideration and withdrawal of the obviousness double patenting rejection is respectfully requested.

CONCLUSION

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,



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